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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,783	04/16/2004	Russell A. Houser	036624-007	4813

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NEWARK, NJ 07102

EXAMINER

HOPKINS, CHRISTINE D

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/825,783

Applicant(s)

HOUSER ET AL.

Examiner

Christine D. Hopkins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 19 Jul 2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- ☐ Notice of Informal Patent Application
- ☐ Other: ____

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-16 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 at line 6 recites the limitation "the shaping device." Claims 15 and 36 at line 2 recite the limitation "the model." There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-13, 16-34, 37-40 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Melvin et al. (U.S. Pub. No. 2004/0064014). Melvin et al. (hereinafter Melvin) disclose methods and devices for improving or correcting structures of the heart. Regarding claims 1-2, 4-7, 11-13, 17, 22, 25-29 and 32-34, Melvin teaches forming an incision in the apical end of the heart, a location of diseased tissue. A "shaping device," or tubular sheath containing a patch is introduced with controlled direction [0328] under guidance from fluoroscopic or echocardiographic techniques [0325]. It is further noted that other potential "identifying" methods include an endoscope equipped with a camera and image shown on a video monitor for providing images to the surgeon to make decisions based on conditions of the cardiac tissue ([0341] and [0490]). The shaping device contains the "patch" **323** having both a concave and convex surface (see Fig. 32), the patch being composed of shape memory metals such as nitinol and stainless steel [0331]. Imaging techniques aid the sheath or "shaping device" advancement through a small open incision (intercostals or subcostal) [0330] into the ventricle, and the sheath releases the patch at a position against the ventricle wall upon its withdrawal from the cardiac tissue [0328]. The initial apical incisions and patch are controlled by purse-string suturing [0329]. Element **330** is considered an attached suture or "protrusion" since it acts to control movement of the patch relative to the ventricular wall [0329], also in accordance with claims 19 and 20.

Furthermore regarding claims 21 and 23-24, the patch having such protrusions ("barbs" or "hooks") may also incorporate a biocompatible adhesive [0313].

In view of claims 3 and 18, "excluding" as taught by the instant specification, entails forming a stitch through the diseased tissue. Thus, the incisions made into the diseased ventricle, which are subsequently controlled by purse-string sutures, are construed as such [0329].

Regarding claims 8 and 9, the step of laser-etching the configured patch is interpreted as trimming and pre-cutting the patch prior to introduction and placement within the heart [0307].

Referring to claims 10 and 30, the instant application teaches a rim of superelastic material on the patch to aid in forming and maintaining an appropriately shaped heart chamber. Since element **321**, comprised of nitinol also acts in the same manner, it is also construed as a rim [312].

Regarding claims 16 and 37, the shape memory metal patch taught by Melvin may possibly be configured by computerized conformation to the shape of the desired location within or outside of the heart, thus determining an appropriate size for the device [0307].

In view of claim 31, passage through the cardiac tissue may be made by puncture from flexible endoscopic forceps [0340].

With reference to claims 38-40 and 46, Melvin teaches a patch **425** (comprising nitinol as discussed above) placed on the surface of the ventricle and attached to the ventricle via several mechanisms such as pins or sutures, thus assisting ventricular

contraction and decompression during systole [0323], but preventing "remodeling" as defined in the instant specification at paragraph [0129].

6. Claims 41-45 and 47-50 are rejected under 35 U.S.C. 102(e) as being anticipated by McCarthy et al. (U.S. Pub. No. 2002/0169359). McCarthy et al. (hereinafter McCarthy) disclose various methods and devices for improving the cardiac function of akinetic tissue. Regarding claims 41-44 and 47-49, McCarthy teaches an enclosure member, or "patch" **61** constructed of a shape memory material and configured to compress or change the shape of a heart chamber. The patch, as a characteristic of its shape memory composition, assumes one shape (circular) prior to being secured to the heart, and immediately following installation, the body reaches a normal temperature thus transforming the patch **61** into an oval shape, imparting compression on the tissue [0205]. Furthermore, regarding claims 45 and 50, a circular polymer sheet ("deployment device") encompassing the patch **61** may be utilized for introduction of the patch. Upon its attachment and subsequent release, patch **61** will return to its original shape.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.


8. Claims 14-15 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melvin et al. (U.S. Pub. No. 2004/0064014) in view of Murphy (U.S. Pub. No. 2005/0020929). Melvin discloses the invention as claimed, see rejection *supra*; however Melvin fails to explicitly disclose saving the images from the echocardiograph or fluoroscopic imaging at different times. Murphy et al. (hereinafter Murphy) teaches a computerized method of creating an interactive model of a diseased heart based on its current conditions. Regarding claims 14 and 35, Murphy teaches imaging of a patient's heart prior to and following treatment, thus disclosing different time intervals. These images may be further saved in a database [0124]. Such imaging techniques include MRI, PET and echocardiography as also suggested by Melvin. Furthermore, saving these images to a database allows other surgeons or users to access and view the images. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have provided images at varying points throughout the treatment process as taught by Murphy, to the imaging techniques presented by Melvin, such that a complete set of characteristics of the improvement of the heart condition can be tracked over time. Such an advantage would further enable the surgeon to improve the treatment process in subsequent surgeries.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Christine D Hopkins
Examiner
Art Unit 3735


Charles A. Marmor, II
Supervisory Patent Examiner
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